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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/405,940 09/27/99 HILLMAN

J PF-0346-1-DI

EXAMINER

HM22/0911

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FWO/DI/G

ART UNIT

PAPER NUMBER

1644

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DATE MAILED:

09/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
09/405,940Applicant(s)
Hillman et al.Examiner
Gerald EwoldtGroup Art Unit
1644☒ Responsive to communication(s) filed on Sep 27, 1999.☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 1, 2, and 13-23 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☐ Claim(s) _____ is/are rejected.☐ Claim(s) _____ is/are objected to.☒ Claims 1, 2, and 13-23 are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152*for transmittal form.*

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4315. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-2 and 13, drawn to a substantially purified T-cell receptor beta protein, variants, and pharmaceutical compositions, classified in Class 424, subclass 185.1 and Class 530, subclass 380.

II. Claims 14, drawn to an antibody, classified in Class 530, subclass 387.1.

III. Claim 15, drawn to a purified agonist of the polypeptide of claim 1, classified in Class 424, subclass 185.1 and Class 530, subclass 350.

IV. Claim 16, drawn to a purified antagonist of the polypeptide of claim 1, classified in Class 424, subclass 185.1 and Class 530, subclass 350.

V. Claim 17, drawn to method of treating cancer with the pharmaceutical composition of claim 13, classified in Class 424, subclass 185.1.

VI. Claims 18 and 21, drawn to method of treating cancer with the agonist of claim 15, classified in Class 424, subclass 185.1.

VII. Claims 19, drawn to method of treating an autoimmune disorder with the antagonist of claim 16, classified in Class 424, subclass 185.1

VIII. Claim 22, drawn to method of detecting a polynucleotide comprising hybridization, classified in Class 435, subclass 6.

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IX. Claim 22, drawn to a method of screening a library, classified in Class 435, subclass 7.1.

X. Claim 23, drawn to a library, classified in Class 530, subclasses 350 and 387.1.

3. Invention I-IV and IX are different products. They are distinct because their structures and/or modes of action are different. Inventions II and IV are mutually exclusive. Therefore, Invention I-IV and IX are patentably distinct.

4. The proteins of Invention I are related to the antibodies of Invention II by virtue of being antigens and the antibodies they bind. Protein antigens and antibodies are physically and functionally distinct chemical entities. In addition to serving as antigens, the peptides may also serve as receptor ligands, hormones, or in assays for the identification same, in addition to pharmaceutical compositions as claimed.

5. Inventions I/III/IV and V/VI/VII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the products as claimed can be used in materially different processes, such as affinity purification or as antigens for antibody production.

5. Inventions IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the library as claimed can be used in materially different processes, such as for subtractive hybridization before screening a different library.

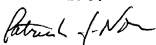
6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Should Applicant elect either Group IX or X, Applicant is further required under 35 U.S.C. § 121 to elect a **specific** type of library, such as one of those listed in claim 23.
8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The different types of libraries are different because they encompass different types of proteins and agents with different functions, characteristics, and properties, e.g., a random peptide library is significantly different than a protein expression library. Therefore, the species of Groups IX and X are independent and patentable over one another.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
10. Any inquiry concerning this communication from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
September 7, 2000


Patrick J. Nolan, Ph.D.
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